

CONSENT FORM

INSTRUCTIONS

1. Follow the Generic Consent Form (pages 10 and 11) closely, touching on all points. Use lay language.
2. If you are dealing with a sensitive topic (i.e., rape, abortion, suicide, terminal illness, sexual abuse, etc.) the consent form must have the names and telephone numbers of qualified counselors or agencies that participants can contact if they become distressed.
3. Other information to be included when appropriate:
 - a. Possible side effects or uncertainties of treatments, tests, experimental drugs, etc.
 - b. Circumstances in which you might need to terminate participants' services regardless of their wishes.
 - c. Additional costs to be incurred by participants.
 - d. Explanation that the research may contain unforeseeable risks.
 - e. Procedures for orderly termination of participation if subject wishes to withdraw and the consequences of that decision.
 - f. Approximate number of participants involved in the study.
4. Consent forms must be typed on departmental letterhead unless you give a good reason for not doing so.
5. Project title must appear on each page of consent form and on any tear-off portion.
6. Write in lay language understandable to your participants. Avoid jargon or technical description.
7. Consent form should be no longer than two pages.
8. Consent - General. Always include the first Consent Statement (page 7) on your Consent Form. Add Audio/Video Consent Form (page 8) if you plan to use audio and/or video tapes.
9. Consent - Pregnant Women. For projects using pregnant women, both the mother and the father must sign the consent form unless: the purpose is to meet the health needs of the mother; the father's identity or whereabouts cannot reasonably be ascertained; he is not reasonably available; or the pregnancy resulted from rape.
10. Consent - Obtained Orally. When consent information is to be presented orally, a transcript must be provided to the Board, and a witness must be present when the transcript is read to the participants. See #11 below.
11. Witness Statement. [Used typically with institutionalized participants, minors, or where consent has been obtained orally. The text of an oral presentation must be approved by the Board; a copy must be given to the subject or the subject's representative, and a copy must be signed by the witness at the time of presentation. A witness is an individual not associated with the researcher and expected to act in the best interests of the participants.]

"I have witnessed the consent process and believe that the participants listed above have been fully informed, understand the project and their role, and have voluntarily agreed to participate."

Witness's Signature

Date

12. Children. See Projects Involving Children (page 13).
13. Copy of consent form must be given to the subject.
14. Consent forms must be kept in a KSU faculty or departmental office for three years beyond end of project.
15. A request for waiver of consent form may require full Board review.

GENERIC CONSENT FORM

[Consent form on KSU departmental letterhead]

Consent Form: [Study Title]

I want to do research on [topic/title of study]. **I want to do this because** [purpose]. **I would like you (to)/(to let your child) take part in this project. If you decide to do this, (you)/(your child) will be asked to** [Describe ways in which human participants will be involved, including length of time (e.g.: two hours over a three week period)].

[If participation involves any discomfort or risk, describe in lay language. If physical injury might result, describe, and include the following:] **Medical Assistance or emergency medical treatment by the University Health Center is provided only to currently registered students. Please be advised that for all others, “911” will be called for physical injuries occurring on the Kent State University main campus. You or your medical insurance will be billed for this service. No other medical treatment or financial compensation for injury from participation in this project is available.**

[If participation involves the possibility of information being disclosed that must be reported, e.g. child abuse or illegal activity] **Confidentiality will be maintained to the limits of the law. Confidentiality may not be maintained if you indicate that you may do harm to yourself or may do/have done harm to others.**

[Describe procedures for anonymity/confidentiality in lay language.]

If (you take)/(your child takes) part in this project [Describe benefits to participants or others in lay language]. **Taking part in this project is entirely up to you, and no one will hold it against (you)/(your child) if you decide not to do it. If (you do)/(your child does) take part, (you)/(he or she) may stop at any time.**

If you want to know more about this research project, please call me at [phone #; include adviser's name and phone number, if appropriate]. **The project has been approved by Kent State University. If you have questions about Kent State University's rules for research, please call Dr. Peter Tandy, Acting Vice President of Research, Division of Research and Graduate Studies (Tel. 330.672.2704).**

You will get a copy of this consent form.

Sincerely,

[Name, title]

B. CONSENT STATEMENT(S)

1. I agree to (take part)/(let my child take part) in this project. I know what (I)/(he or she) will have to do and that (I)/(he or she) can stop at any time.

Signature

Date

Waiver or Alteration of Informed Consent

Informed consent assures that participants understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. The basic elements of informed consent (e.g., explanation of the study's purpose, description of foreseeable risks and benefits, description of the extent to which confidentiality will be maintained, explanation of whom to contact with questions, statement that participation is voluntary and may be discontinued at any time, etc.) are outlined in federal guidelines (Title 45, Code of Federal Regulations, Part 46). In rare instances, the guidelines allow IRBs to approve a consent procedure that does not include, or alters, some of the elements of informed consent. To request an approval for a waiver or alteration of informed consent, the investigator must document that the proposed study meets the following criteria:

1. The research involves no more than minimal risk to participants;
2. The waiver or alteration will not adversely affect the rights and welfare of participants;
3. The research could not practicably be carried out without the waiver or alteration (e.g., some research on child abuse and neglect or on runaway teens could not be carried out without a waiver of parental consent).
4. Whenever appropriate, the participants will be provided with additional pertinent information after they have participated in the study.

Waivers cannot be granted because the investigator lacks the resources (e.g., personnel, time, money) needed to obtain informed consent. In most instances, granting a waiver of informed consent involves full board review.

Passive Consent

Passive consent is when parents are sent a letter explaining the research and are told that unless they return the letter the child will be enrolled in the study. This is different from a waiver because parents are notified about the research through a letter. The Board's concern with this type of consent is that there is no guarantee that parents see the letter. Unless justification beyond inconvenience is provided, passive consent will not be allowed.